5068 West Plano Parkway Suite 122
Plano, Texas 75093
Phone: (972) 931-5100

DATE OF REVIEW: 03/17/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Neurontin 600mg, 2 tablets PO BID plus one tablet PO QHS

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This case was reviewed by a Texas licensed MD, specializing in Physical Medicine & Rehabilitation. The physician advisor has the following additional qualifications, if applicable:

ABMS Physical Medicine & Rehabilitation

REVIEW OUTCOME:

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ **Upheld**

Health Care Service(s) in Dispute	CPT Codes	Date of Service(s)	Outcome of Independent Review
Neurontin 600mg, 2 tablets PO BID plus one tablet PO QHS		-	Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

No	Document Type	Provider or Sender	Page Count	Service Start Date	Service End Date
1	IRO Request		7	02/12/2010	03/01/2010
2	Diagnostic Test	Medical Center	5	09/27/2007	09/27/2007
3	Diagnostic Test	Imaging Garland	2	11/13/2007	11/13/2007
4	Lab Report	Laboratories	1	12/09/2009	12/09/2009
5	Diagnostic Test	MD	1	04/18/2008	04/18/2008
6	Office Visit Report	MD	33	04/04/2008	02/10/2010
7	Office Visit Report	MD	4	06/17/2008	06/17/2008
8	Impairment/Disability Rating Report	MD	2	08/08/2008	08/08/2008
9	Peer Review Report	MD	7	10/05/2009	10/05/2009
10	Initial Denial Letter		4	02/08/2010	02/24/2010

11	Initial Denial Letter		9	02/08/2010	02/24/2010
12	Initial Request	MD	3	01/29/2010	02/03/2010
13	Office Visit Report	MD	6	12/21/2009	02/02/2010
14	Archive		1		
15	IRO Record Receipt	TDI-DWC	4	02/25/2010	02/25/2010

PATIENT CLINICAL HISTORY [SUMMARY]:

SUMMARY OF MEDICAL DOCUMENTATION

HEALTHCARE PROVIDERS:

1. M.D.
   a. 04/04/08. Complaints of back pain due to overuse injury to thoracic spine while lifting 50 lbs bag, status post left T8-T9, T10-T11, T11-T12 intercostal nerve blocks in January 2008 and February 2008. No success. Impression lower thoracic spine injury, severe deconditioned state, chronic pain with medical psychological features.
   b. 04/18/08. Functional restoration program planned. Neurontin, Relafen, Lexapro, Restoril prescribed.
   c. Electrodiagnostic testing 04/18/08. No evidence of radiculopathy.
   d. 05/09/08. She is undergoing phase 2 functional restoration program.
   e. 06/08/08. Bilateral intercostal nerve blocks T8 through T12.
   f. 06/17/08 follow-up. No objective functional deficits noted. Suffers from limitation, rotation 20 degrees to the right, 10 degrees to left.
   g. Note on 08/08/08 reports she was ready to return back to full time gainful employment . Medication included Skelaxin, Wellbutrin, Klonopin, Neurontin, and Relafen. She was given a 5% whole person impairment rating, which was not a disabling reading.
   h. Note on 11/14/08 reported subjective complaints of pain on exam, but no objective measures or functional deficits. She was working full time.
   i. 02/06/09. Medication included Neurontin, Klonopin, Medrol Dosepak prescribed. Amrix prescribed. There were some subjective range of motion deficits, but otherwise unremarkable exam.
   j. 03/06/09. Medial branch blocks planned at T9 through T12 on the left side.
   k. 06/26/09. She was not working at that point in time. She had subjective complaints of back pain. No objective measured functional deficits.
   l. 09/23/09 follow-up. Ongoing complaints of pain. Subjective tenderness in thoracic lumbar region with some spasms, but no objective measured functional deficits. Wellbutrin, Klonopin, Neurontin, Amrix, and Restoril continued.
   m. 11/20/09 follow-up. Elavil prescribed. Dorsal column stimulator recommended.
   n. 01/27/10. Recommended dorsal spinal cord stimulator. Preauthorization regarding use of Neurontin.
   o. 02/01/10. Phone conference reporting that there was findings of thoracic radiculopathy in his diagnosis.
   p. 02/08/10 medical review institute. Neurontin was not recommended, no reports of side effects with the medication with mental status.
   q. 02/10/10 follow-up. Ongoing subjective chronic thoracic chest wall pain. She complains of mid back pain lateralizing the left chest wall. No numbness, no tingling. Medication included Lexapro, Abilify, Neurontin, and Valium.

2. M.D.: Assessment 10/05/09. Impression was chronic pain syndrome, myofascial dysfunction, possibly intercostals neuralgia, secondary to anxiety depression preexisting history of depression. He opined the treatment was reasonable and medically necessary related to the injury on 07/18/07. There was possible cognitive dysfunction related to the medication and possibly related to her pain. He reported temazepam, clonazepam, Amrix medically necessary. No further physical therapy, chiropractic therapy or diagnostic testing is reasonable or medically necessary. Intercostal injections are not reasonably medically necessary. However, Botox injection may be beneficial.

3.
   a. 12/21/09. Medication included Neurontin, valium, Amrix, Restoril, Abilify, Lexapro, and Vyvanse.
   b. 01/14/10 follow-up. Her back pain better with Evoxac and Neurontin. She was on Vyvanse and Valium for her chronic pain syndrome and depression. No objective abnormal examination findings.

c. 02/10/10 follow-up. No objective exam findings reported.

4. Letter from reporting Neurontin helps her function and controls severe pain.

5. 02/24/10. The Neurontin was not reasonably medically necessary. Discussion regarding the dosing was too high with the Neurontin medically necessity not established

DIAGNOSTIC STUDIES:
1. CT scan abdomen and pelvis 09/27/07. Indeterminate low density within the liver. Recommended non-emergent abdominal ultrasound. Mesenteric adenitis and pancreatic divisum. Indeterminate benign appearing lesion right acetabulum. No evidence of bowel obstruction, findings compatible with constipation. No acute cardiopulmonary process. MRI abdomen 10/08/07 probable three small hemangiomas in liver. Follow-up MRI in three months.
2. 11/13/07 MRI lumbosacral spine. Multilevel degenerative joint disease, degenerative disc disease with no reported nerve root entrapment.
3. MRI thoracic spine 11/13/07. No acute changes and findings of mild kyphosis and anterior osteophytes.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The medical necessity of this medication has not been established based upon documentation reviewed. Diagnostic workup has been negative for any findings of pathology that would be associated with neuropathic pain in terms of radiculopathy or nerve trauma. MRI was negative for nerve root entrapment. Electrodiagnostic studies were negative for radiculopathy. Past intercostals nerve blocks have been negative regarding measured functional gains and ability to decrease medication use. Neurontin is classified as a treatment modality for neuropathic pain, of which this finding is not appreciated in the medical records reviewed. ODG guidelines recommend use of Neurontin for post hepatic neuralgia, diabetic painful neuropathy, fibromyalgia, history of spinal cord injury, lumbar spinal stenosis. These diagnoses have also not been established in the documentation reviewed.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

Gabapentin (Neurontin®, Gabarone™, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study.

Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. (Arnold, 2007)

Specific pain states:

Acute pain: There is limited evidence to show that this medication is effective for acute pain, and for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-

anxiety effect, is accompanied by increased sedation and dizziness. (Peng, 2007) (Buvanendran, 2007) (Menigaux, 2005) (Pandey, 2005)

Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. (Levendoglu, 2004)

CRPS: Recommended as a trial. (Serpell, 2002)

Fibromyalgia: Recommended as a trial. (Arnold, 2007)

Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study. (Yaksi, 2007)

Side-Effect Profile: Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007) (Attal, 2006) Weight gain is also an adverse effect.

Dosing Information:

Postherpetic neuralgia – Starting regimen of 300 mg once daily on Day 1, then increase to 300 mg twice daily on Day 2; then increase to 300 mg three times daily on Day 3. Dosage may be increased as needed up to a total daily dosage of 1800 mg in three divided doses. Doses above 1800 mg/day have not demonstrated an additional benefit in clinical studies. (Neurontin package insert)

Diabetic neuropathy (off-label indication) – Gabapentin dosages range from 900 mg to 3600 mg in three divided doses (Backonja, 2002) (Eisenberg, 2007). Gabapentin is 100% renally excreted.

Recommended Trial Period: One recommendation for an adequate trial with gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggest that if inadequate control of pain is found, a switch to another first-line drug is recommended. Combination therapy is only recommended if there is no change with first-line therapy, with the recommended change being at least 30%. (TCA, SNRI or AED). (Jensen, 2006) (Eisenberg, 2007)

Weaning and/or changing to another drug in this class: Gabapentin should not be abruptly discontinued, although this recommendation is made based on seizure therapy. Weaning and/or switching to another drug in this class should be done over the minimum of a week. (Neurontin package insert) *When to switch to pregabalin:* If there is evidence of inadequate response, intolerance, hypersensitivity or contraindications. There have been no head-to-head comparison trails of the two drugs.

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☐ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**

☐ **MILLIMAN CARE GUIDELINES**

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**

☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**

☐ **TEXAS TACADA GUIDELINES**

☐ **TMF SCREENING CRITERIA MANUAL**

☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**

☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**

TEXAS DEPARTMENT OF INSURANCE COMPLAINT PROCESS: The Texas Department of Insurance requires Independent Review Organizations to be licensed to perform Independent Review in Texas. To contact the Texas Department of Insurance regarding any complaint, you may call or write the Texas Department of Insurance. The telephone number is 1-800-578-4677 or in writing at: Texas Department of Insurance, PO Box 149104 Austin TX, 78714. In accordance with Rule 102.4(h), a copy of this Independent Review Organization (IRO) Decision was sent to the carrier, the requestor and claimant via facsimile or U.S. Postal Service from the office of the IRO on 03/17/2010.